UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/833,506	04/07/97	WEBBER	R 12842

EXAMINER	
HUFF, S	
ART UNIT	PAPER NUMBER
1642	25

DATE MAILED: 02/15/01

HM12/0215

THEODORE J BIELEN JR
BIELEN PETERSON & LAMPE
1991 N CALIFORNIA BLVD
SUITE 720
WALNUT CREEK CA 94596

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/833,506	Applicant(s) Webber
	Examiner Sheela J. Huff	Group Art Unit 1642

☒ Responsive to communication(s) filed on *Dec 12, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 12/12/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/833506 is acceptable and a CPA has been established. An action on the CPA follows. Claims 1-21 are pending.

Sequence Listing

2. Applicant is requested to insert SEQ ID No. next to the sequences in claims 3 and 10.

Specification

3. A substitute specification excluding the claims is still required pursuant to 37 CFR 1.125(a) because the amendment filed on 5/4/00 is too long.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the

substitute specification relative to the specification at the time the substitute specification is filed.

Claim Rejections - 35 USC § 112

4. Claims 1-21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Item 4e of paper no. 22, mailed 7/10/00 is overcome by applicant's amendment.

a. In claim ~~21~~ 22-23, the terminology "regions of human iNOS" renders the claim vague and indefinite. What does applicant mean by "regions"? How many amino acids are there is a "region"?

d. In claim ~~2~~ 23, what does applicant mean by "polymers as artificial antibodies" and "phage display binding sites"? Polymers are polymers (organic compounds) not antibodies,

h. In claim ~~8~~ 3029 it is not clear what applicant means by "mimics".

~~**i.** In claim 9, it is not clear what applicant means by "analogue".~~

~~**j.** In claim 21, what does applicant mean by "vehicle"?~~

~~**k.** Claims 5 and 12 are duplicates.~~

Applicant did not respond to the above rejections.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims ~~1-21~~ 2 2-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16 and 17 of copending Application No. 08/634332. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to immunoassays. The only difference between the two is that the specific binding entity of the instant invention can be other things in addition to an antibody.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant did not response to this rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22-23, 26 - 28, 4039

8. Claims ~~1-7, 12, 18 and 21~~ remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/23038 (Moncada et al) or Kobzik et al Am. J. Respir. Cell Mol. Biol. vol. 9 p. 371 (1993) or Fujisawa et al J. Neurochemistry vol. 64 p. 85 (1995). The reasons for this rejection are of record in paper no. 5, mailed 5/8/98.

Applicant did not respond to this rejection.

22, 26 - 28, 4039

9. Claims ~~1, 4-7, 12, 18 and 21~~ remain rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda Tojo Medical Journal vol. 65 p. 433 (6/95). The reasons for this rejection are of record in paper no. 5, mailed 5/8/98.

Applicant did not respond to this rejection

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22-23 26-28, 4039

12. Claims 1-2, 4-7, 12, 18 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda Tojo Medical Journal vol. 65 p. 433 (6/95) or Kobzik et al Am. J. Respir. Cell Mol. Biol. vol. 9 p. 371 (1993) or Fujisawa et al J. Neurochemistry vol. 64 p. 85 (1995). The reasons for this rejection are of record in paper no. 5, mailed 5/8/98.

Applicant did not respond to this rejection.

Claim Rejections - 35 USC § 112

13. Claims 1-21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Item 13c of paper no. 22, mailed 7/10/00 has been overcome by applicant's amendment.

a. In claims 1 and 8 and 21, "said specific binding entity" in line 5 lacks antecedent basis.

b. In claims 2 and 15-16 and 19-20, lines 1-2 "said specific binding entity" lacks antecedent basis.

Applicant did not respond to this rejection.

14. Claims 2 and 9 remain objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The definition of "binding entity" in claim 2 does not further limit the specific binding entity in claim 1, which is a monoclonal antibody..

Applicant did not respond to this objection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

15. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The terminology "imprinted artificial antibodies" is not found in the specification. Applicant is asked to point to where in the specification this is found or remove the terminology.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday and Thursday from 5:30am to 2:00pm.

If attempts to teach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Tony Caputa, can be reached on (703)308-3995.

The FAX phone number for the group is (703)308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff

February 8, 2001

Sheela J. Huff

Primary Examiner